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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,191	11/24/2003	Richard Gribbons	PA1700 US	6737

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

HOUSTON, ELIZABETH

ART UNIT	PAPER NUMBER
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3731

NOTIFICATION DATE	DELIVERY MODE
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05/01/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary

Application No.

10/722,191

Applicant(s)

GRIBBONS ET AL.

Examiner

Elizabeth Houston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/07/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "36" has been used to designate both the "stop" and the "guidewire lumen in the guide member". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 1 and 3 is objected to because of the following informalities: spelling typos: In the last line of claim 1, "rotatably " should be changed to rotatable; In claim 3, "communitcation" should be changed to communication. Appropriate correction is required.

Double Patenting

3. Claim 1 and 2 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,905,477 in

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view of Fischell (USPN 5,334,187). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent disclose all the limitations in the instant claims except for the limitation, "the guide member having an outer member and an inner member, the outer member being selectively rotatably around the inner member. Fischell discloses a guide member with an inner member that is a tube (48) defining the guidewire lumen. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the tube into the patented device since it is an old and well-known feature to have a tubular member to provide support for the guidewire lumen. The combination meets the limitations of the pending claims in that the outer member is the housing and the inner member is the tube (48). When the outer member is rotated, it will inherently rotate around the inner member. Fischell also discloses that the keel has a guidewire lumen.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Crittenden et al. (USPN 4,988,356).**

1. Crittenden discloses a catheter and guide wire exchange system comprising:

- a. An elongate flexible catheter shaft (10) having proximal and distal shafts and first (26) and second (22) lumens extending there through, the first lumen being open at the shaft distal end (18) and being sized and shaped to slidably receive a guide wire;
- b. A longitudinal guide way (28) formed in the proximal shaft to enable transverse access to the first lumen through the proximal shaft, the guide way extending along a major portion of the length of the proximal shaft from a location adjacent a proximal end (24) of the proximal shaft to a distal terminal end (32) proximal of a distal end of the proximal shaft, thereby defining an uncut distal segment of the proximal shaft (34);
- c. A balloon mounted about a distal segment of the distal shaft (20), the balloon being in fluid communication with the second lumen;
- d. And a guide member (12) mounted on the proximal shaft and having a longitudinal catheter passageway (44, Fig. 7) extending there through for slidably receiving the catheter shaft and a guidewire passageway (the lumen defined by tubular member 48) for slidably receiving a guidewire for merging the guide wire and the catheter by guiding the guide wire transversely through the guide way and into the first lumen and for separating the guide wire and catheter by guiding the guide wire transversely out of the first lumen through said guide way, the guide member including a keel (54) for tracking the guide way. The guide member has an inner member (tube 48) and an outer member (housing 12). When

the guide member is rotated by the user, the outer member will rotate around the inner member.

6. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. (USPN 5,334,187).

2. Crittenden discloses a catheter and guide wire exchange system comprising:

e. An elongate flexible catheter shaft (20) having proximal and distal shafts and first (23) and second (22) lumens extending there through, the first lumen being open at the shaft distal end (55) and being sized and shaped to slidably receive a guide wire (12);

f. A longitudinal guide way (25) formed in the proximal shaft to enable transverse access to the first lumen through the proximal shaft, the guide way extending along a major portion of the length of the proximal shaft from a location adjacent a proximal end of the proximal shaft to a distal terminal end proximal of a distal end of the proximal shaft, thereby defining an uncut distal segment of the proximal shaft (23);

g. A balloon mounted about a distal segment of the distal shaft (54), the balloon being in fluid communication with the second lumen;

h. And a guide member (30) mounted on the proximal shaft and having a longitudinal catheter passageway (23) extending there through for slidably receiving the catheter shaft and a guidewire passageway (22) for slidably receiving a guidewire for merging the guide wire and the catheter by guiding the

guide wire transversely through the guide way and into the first lumen and for separating the guide wire and catheter by guiding the guide wire transversely out of the first lumen through said guide way, the guide member including a keel (47) for tracking the guide way. The guide member has an inner member (tube 48 or 45) and a outer member (outer housing). Even though the outer member is fixed to the inner member, when the user rotates the guide member, the outer member will rotate around the inner member. The keel (47) has a passageway for receiving the guidewire.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh

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4/20/07

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ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

4/26/07